

Remarks

I. Status and Nature of the Amendments

Claims 1-31 are presently pending in this application, and claims 32-62 have been cancelled. No claim numbered claim 63 has been presented. Due to Applicants' election of the species "cytokine," claims 2-4, 10-15 and 18-25 have been temporarily withdrawn from consideration. Thus, only claims 1, 5-9, 16, 17, and 26-31 have been examined. All examined claims have been rejected, as indicated below.

Claim 1 has been amended to recite that for at least one target analyte being detected, the signal in the initial detection time duration is outside the known dynamic range of the detector's assay for that target analyte, and that in such occurrence, the computer system varies the detection time duration relative to the initial detection time duration until the detected signal for such analyte is within the known dynamic range of said detector's assay for that target analyte, and then causes the computer system to report the presence, absence, activity or concentration of such target analyte. Support for this amendment can be found in original claim , and throughout the specification (see, e.g., page 10, line 3-14). No new matter has been added by the requested amendment.

II. The Rejection of Claims 1, 5-9, 16, 17, and 26-31 Under 25 U.S.C. § 112, Second Paragraph

Claims 1, 5-9, 16, 17, and 26-31 have been rejected under 25 U.S.C. § 112, second paragraph as indefinite in light of a perceived deficiency relating to step (C), part (1), of claim 1. Specifically, the Examiner has suggested that this provision of claim 1 is indefinite in not clarifying how the detection time is to be varied. The Examiner has questioned whether the initial detection time is increased or decreased, or whether a second detection occurs. Clarification has been requested.

Applicants respectfully submit that claim 1 (and its dependent claims) is fully definite, and that the issue identified by the Examiner relates to claim scope and not the indefiniteness of any claim term. Applicants respectfully submit that claims 1, 5-9, 16, 17, and 26-31 encompass methods in which the “varying” of the detection time is accomplished by either (a) increasing or decreasing the initial detection time, or (b) causing a second detection to occur. Claim 1 is thus generic to claims 2 and 3/4, which the Examiner has held are separate and distinct inventions.

Applicants respectfully submit that the rejection of claims 1, 5-9, 16, 17, and 26-31 under 25 U.S.C. § 112, second paragraph as indefinite may be properly withdrawn.

III. The Rejection of Claims 1, 5-9, 29 and 31 under 25 U.S.C. § 102(e) in Light of Herron *et al.* (U.S. 6,287,871)

Claims 1, 5-9, 29 and 31 have been rejected under 25 U.S.C. § 102(e) in light of Herron *et al.* (U.S. Patent No. 6,287,871). Specifically, the Examiner has stated that with respect to step (C), (1) and (2), “the Examiner interprets step (C), (1) or (2) as recited in claim 1, line 24.” The precise meaning of the Examiner’s comment is unclear.

Applicants respectfully traverse and request reconsideration. The teachings of Herron *et al* have been discussed in Applicants Response to the Official Action of September 24, 2003, which discussion is herein incorporated by reference. Applicants respectfully submit that the present claims recite a process in which at the presence, absence, activity or concentration of two or more target analytes is determined, and in which at least one of such target analytes is present at a concentration that results in a detected signal that is outside the known dynamic range of the detector’s assay for that target analyte. The claim recites that the process involves varying the duration of signal detection for each analyte until the detected signal is within the dynamic range of the detector’s assay for that analyte.

Applicants respectfully submit that the presently claimed invention thus differs from the method disclosed by Herron *et al.* in the following respects:

1. Herron *et al.* do not teach that the reported presence, absence, activity or concentration of each target analyte is to be determined using the emissions or quenchings of light signals falling *within the known dynamic range of the detector's assay for that target analyte*;
2. Herron *et al.* teach only the passive use of a CCD detection means, and do not teach using a computer system to ensure that the concentration of an analyte is calculated with reference signals generated from within the dynamic range of the detector's assay for a target analyte;
3. Herron *et al.* do not teach either that at least one of the analytes being assayed will generate a detected signal that falls outside of the dynamic range of the assay being used to detect that analyte.

Applicants respectfully submit that the present claims are not anticipated by the Herron *et al.* patent. Applicants therefore respectfully submit that the rejection of claims 1, 5-9, 29 and 31 as anticipated by Herron *et al.* may be properly withdrawn.

IV. The Rejection of Claims 16, 17, 27, 28 and 30 Under 25 U.S.C. § 103(a)

A. The Rejection of Claims 16 and 17 In Light of Herron *et al.* (U.S. 6,287,871) In View of Lehmann *et al.* (U.S. 5,939,281)

The teachings of the Herron *et al.* Patent (U.S. 6,287,871) have been discussed above. The Lehmann *et al.* Patent (U.S. 5,939,281) is stated to disclose the use of specific binding reagents, such as antibodies, for detecting the concentration of a cytokine. Applicants submit that the combined teachings of the cited references fail to render obvious the present invention since they do not disclose or suggest the claimed use of a computer system to compare the signal elicited by an analyte of unknown concentration with the signal that would be elicited by that analyte within the dynamic

range of the assay being used, and to independently alter the duration of signal detection for each assay to ensure that the detected signal falls within the dynamic range of the detector's assay.

Accordingly Applicants respectfully submit that the cited Lehmann *et al.* Patent fails to remedy the deficiency of the primary reference, and that the combined references thus fail to render Claims 16 and 17 obvious. Applicants therefore submit that the rejection of Claims 16 and 17 under 35 U.S.C. § 103(a) in light of Herron *et al.* (U.S. 6,287,871) and Lehmann *et al.* (U.S. 5,939,281) may be properly withdrawn.

B. The Rejection of Claims 27 and 28 In Light of Herron *et al.* (U.S. 6,287,871) In View of Campbell *et al.* (U.S. 4,946,958)

The teachings of the Herron *et al.* Patent (U.S. 6,287,871) have been discussed above. The Campbell *et al.* Patent (U.S. 4,946,958) is stated to disclose the use of a chemiluminescent label in the analysis, assay or location of proteins. As in the case of the Lehmann *et al.* Patent, Applicants submit that the combined teachings of the Herron *et al.* Patent and the Campbell *et al.* Patent fail to render obvious the present invention since they do not disclose or suggest the claimed use of a computer system to compare the signal elicited by an analyte of unknown concentration with the signal that would be elicited by that analyte within the dynamic range of the assay being used, and to independently alter the duration of signal detection for each assay to ensure that the detected signal falls within the dynamic range of the detector's assay

Applicants therefore submit that the rejection of Claims 27 and 28 under 35 U.S.C. § 103(a) in light of Herron *et al.* (U.S. 6,287,871) and Campbell *et al.* Patent (U.S. 4,946,958) may be properly withdrawn.

C. The Rejection of Claim 30 In Light of Herron *et al.* (U.S. 6,287,871) In View of McMillan *et al.* (U.S. 6,057,163)

The teachings of the Herron *et al.* Patent (U.S. 6,287,871) have been discussed above. The McMillan *et al.* Patent (U.S. 6,057,163) is stated to disclose the use of a

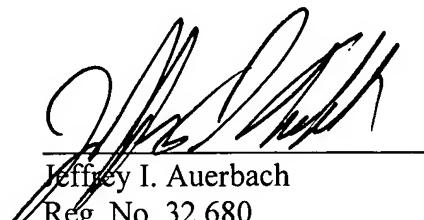
microwell plate for detecting the amount of light emitted by a plurality of samples. As in the case of the Lehmann *et al.* and Campbell *et al.* Patents, Applicants submit that the combined teachings of the Herron *et al.* Patent and the McMillan *et al.* Patent fail to render obvious the present invention since they do not disclose or suggest the claimed use of a computer system to compare the signal elicited by an analyte of unknown concentration with the signal that would be elicited by that analyte within the dynamic range of the assay being used, and to independently alter the duration of signal detection for each assay to ensure that the detected signal falls within the dynamic range of the detector's assay

Applicants therefore submit that the rejection of Claim 30 under 35 U.S.C. § 103(a) in light of Herron *et al.* (U.S. 6,287,871) and McMillan *et al.* (U.S. 6,057,163) may be properly withdrawn.

V. Concluding Remarks

Having now responded to all of the Examiner's rejections, Applicants respectfully submit that the present application is in condition for Allowance, and earnestly solicit early notice of such favorable action. The Examiner is respectfully invited to contact the undersigned with respect to any issues regarding this application.

Respectfully Submitted,



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